

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Ashley N. Sturgeon, Reg. 64,819 And Ms. Jean M. Dickman, Reg. 48,538 on June 16, 2010 and June 14, 2010, respectively

The application has been amended as follows:

1. (Currently Amended) A method for testing fecal samples from persons for diagnosis, the method comprising:

obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome;

diluting the sample;

determining that the sample contains an elevated level of lactoferrin compared to a lactoferrin level in a healthy control;

measuring the sample for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA);

measuring the sample for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA);

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upon determining that the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies compared to an anti-*Saccharomyces cerevisiae* antibody level in a healthy control and not an elevated level of anti-neutrophil cytoplasmic antibodies, diagnosing the person with Crohn's disease; and

upon determining that the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies compared to an anti-neutrophil cytoplasmic antibody level in a healthy control and not an elevated level of anti-*Saccharomyces cerevisiae* antibodies, diagnosing the person with ulcerative colitis.

30. (Currently Amended) A method for testing fecal samples from persons for diagnosis, the method comprising:

obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome;

diluting the sample;

contacting the diluted sample with immobilized polyclonal antibodies to endogenous lactoferrin to create a first treated sample;

contacting said first treated sample with enzyme-linked polyclonal antibodies such that the enzyme-linked polyclonal antibodies are allowed to bind to captured endogenous lactoferrin creating an enzyme-linked antibody bound sample;

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adding a substrate to the enzyme-linked antibody bound sample to create a readable sample;

determining the optical density of said readable sample at 450 nm;

determining that the sample contains an elevated level of lactoferrin compared to a lactoferrin level in a healthy control;

measuring the sample for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA);

measuring the sample for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA);

upon determining that the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies compared to an anti-*Saccharomyces cerevisiae* antibody level in a healthy control and not an elevated level of anti-neutrophil cytoplasmic antibodies, diagnosing the person with Crohn's disease; and

upon determining that the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies compared to an anti-neutrophil cytoplasmic antibody level in a healthy control and not an elevated level of anti-*Saccharomyces cerevisiae* antibodies, diagnosing the person with ulcerative colitis.

31. (Previously Presented) The method of claim 30, further comprising:
contacting the sample with antigens of *Saccharomyces cerevisiae* to create a second treated sample;

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contacting the second treated sample with polyvalent antibodies to human immunoglobulin conjugated to an enzyme such that the polyvalent antibodies are allowed to bind to capture anti-*Saccharomyces cerevisiae* antibodies creating an enzyme-linked antibody bound sample;

adding a substrate to the enzyme-linked antibody bound sample to create a readable sample; and

determining the optical density of the readable sample.

32. (Currently Amended) A method for testing fecal samples from persons for diagnosis, the method comprising:

obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome;

diluting the sample;

contacting the sample with neutrophil cytoplasmic antigens to create a treated sample;

contacting the treated sample with polyvalent antibodies to human immunoglobulin such that the enzyme-linked polyvalent antibodies are allowed to bind to capture anti-neutrophil cytoplasmic antibodies creating an enzyme-linked antibody bound sample;

adding an enzyme substrate to the enzyme-linked antibody bound sample to create a readable sample;

determining an optical density of the readable sample at 450 nm;

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determining that the sample contains an elevated level of lactoferrin
compared to a lactoferrin level in a healthy control;

measuring the sample for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA);

measuring the sample for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA);

upon determining that the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies compared to an anti-*Saccharomyces cerevisiae* antibody level in a healthy control and not an elevated level of anti-neutrophil cytoplasmic antibodies, diagnosing the person with Crohn's disease; and

upon determining that the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies compared to an anti-neutrophil antibody level in a healthy control and not an elevated level of anti-*Saccharomyces cerevisiae* antibodies, diagnosing the person with ulcerative colitis.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1645

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